

§ 520.2325b

per pound per day in cattle and calves depending on the age, class of animal, ambient temperature, and other factors. A withdrawal period has not been established for sulfaquinoxaline in preruminating calves. Do not use in calves to be processed for veal. Not for use in lactating dairy cattle. Do not give to chickens, turkeys or cattle within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Make fresh drinking water daily.

[48 FR 3964, Jan. 28, 1983, as amended at 48 FR 26762, June 10, 1983; 55 FR 29843, July 23, 1990; 59 FR 28769, June 3, 1994; 59 FR 33197, June 28, 1994; 61 FR 24443, May 15, 1996; 61 FR 63711, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 65 FR 10705, Feb. 29, 2000; 69 FR 41427, July 9, 2004; 69 FR 60547, Oct. 12, 2004; 74 FR 36112, July 22, 2009; 78 FR 17596, Mar. 22, 2013]

§ 520.2325b Sulfaquinoxaline drench.

(a)–(b) [Reserved]

(c) *Sponsor*. See No. 050749 in § 510.600(c) of this chapter.

(d) *NAS/NRC status*. The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency information. Applications must be accompanied by a written commitment to undertake the human safety studies required by FDA.

(e) *Conditions of uses*. As a 25-percent sulfaquinoxaline soluble powder.

(1) For the control and treatment of outbreaks of coccidiosis in cattle and calves caused by *Eimeria bovis* or *E. zurnii*.

(2) Give one teaspoon of 25 percent sulfaquinoxaline soluble powder for each 125 pounds of body weight for 3 to 5 days as a drench.

(f) *Limitations*. For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

[48 FR 3964, Jan. 28, 1983, as amended at 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994]

21 CFR Ch. I (4–1–14 Edition)

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications*. Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer one tablet orally per 4 pounds of body weight.¹

(2) *Indications for use*. Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.¹

(3) *Limitations*. Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.¹

[43 FR 60895, Dec. 29, 1978]

§ 520.2340 Tepoxalin.

(a) *Specifications*. Each tablet contains 30, 50, 100, or 200 milligrams (mg) tepoxalin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 10 mg per kilogram (/kg) daily; or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 34795, June 11, 2003]

§ 520.2345 Tetracycline.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications*. Each capsule contains 50, 100, 125, 250, or 500 milligrams (mg) tetracycline hydrochloride.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

Food and Drug Administration, HHS

§ 520.2345d

(b) *Sponsor*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000009: 250 mg per capsule.

(2) No. 000069: 125, 250, or 500 mg per capsule.

(c) *Conditions of use in dogs*—(1) *Amount*. 25 mg per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 50182, Aug. 26, 2005, as amended at 73 FR 18442, Apr. 4, 2008]

§ 520.2345b Tetracycline tablets.

(a) *Specifications*. Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor*. For 100, 250, or 500 milligrams per tablet, see No. 000069 in § 510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations*. Administer orally; continue treatment until symptoms of the disease have subsided and temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992]

§ 520.2345c Tetracycline boluses.

(a) *Specifications*. Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsors*. See No. 053501 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See No.

000009 in § 510.600(c) of this chapter for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See § 556.720 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations*. Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline.

(iii) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use specified in paragraph (d)(1)(i) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Amount*. 10 milligrams per pound of body weight per day in two divided doses.

(i) *Indications for use*. Treatment of bacterial pneumonia caused by organisms susceptible to tetracycline, bacterial enteritis caused by *E. coli*, and salmonella organisms susceptible to tetracycline.

(ii) *Limitations*. Administer orally for not more than 5 days; do not slaughter animals for food within 12 days of treatment; use as sole source of tetracycline.

[57 FR 37328, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.2345d Tetracycline powder.

(a) *Specifications*. Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.

(b) *Sponsors*. See sponsors listed in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section:

(1) No. 000069: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) No. 054628: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.